DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 10, 2014

Elizabeth Greene
Regulatory Affairs Manager
Stimwave Technologies Incorporated
9375 East Shea Boulevard
Suite 147
Scottsdale, Arizona 85260

Re: K141399
Trade/Device Name: Freedom Spinal Cord Stimulator (SCS) System
Regulation Number: 21 CFR 882.5880
Regulation Name: Stimulator, Spinal-Cord, Implanted (Pain Relief)
Regulatory Class: Class II
Product Code: GZB
Dated: September 5, 2014
Received: September 8, 2014

Dear Ms. Greene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141399

Device Name
Freedom Spinal Cord Stimulator (SCS) System

Indications for Use *(Describe)*
The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is solely used for trial stimulation (no longer than 30 days) of the permanent FRE4-A001 device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**

**for**

**Freedom Spinal Cord Stimulator (SCS) System**

## 1. Submission Sponsor

Stimwave Technologies Incorporated
420 Lincoln Road
Suite 365
Miami Beach
Florida 33139
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Regulatory Affairs Manager

## 2. Date Prepared

May 27, 2014

## 3. Device Identification

| | |
|---|---|
| Trade/Proprietary Name: | Freedom Spinal Cord Stimulator (SCS) System |
| Common/Usual Name: | Spinal Cord Stimulator |
| Classification Name: | Stimulator, Spinal-Cord, Implanted (Pain Relief) |
| Classification Regulation: | 882.5880 |
| Product Code: | GZB |
| Device Class: | Class II |
| Classification Panel: | Neurology |

## 4. Legally Marketed Predicate Device(s)

Medtronic Mattrix 3271/3272 Neuromodulation System (K934065)
Medtronic Xtrel, Model Number 3425 Receiver (K883780)
ANS Renew Neurostimulation System Transmitter, Model 2508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343 (K000852)

## 5. Device Description

The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord SCS System (System) is used for spinal column neural stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an electrical energy field that

acts on nerves near the dorsal column of the spine. The System is comprised of an implantable stimulator (Freedom-4 Stimulator) and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device. The System is implanted only following a successful trial period with the Trial Freedom-4 Stimulator.

| **Freedom-4 Stimulator (Receiver Kit)** | |
|---|---|
| Freedom-4 Stimulator | A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed percutaneously in the patient's epidural space. The Stimulator has four (4) electrodes. |
| Stylet(s) | A stainless steel wire with a nylon hub that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Four (4) stylets are provided in the Receiver Kit, two straight and two bent with diameters of 0.25 mm or 0.30 mm. |
| Tuohy Needle | A 14-gauge stainless steel needle that is inserted into the epidural space of the patient and acts as a conduit to guide the introducer sheath. |
| Introducer Sheath | A PEBAX sheath that slides over the Tuohy needle before insertion, and acts as a conduit for passage of the stimulator into the epidural space. The introducer sheath is RF transparent, allowing the transmission of wireless power to the Stimulator for intraoperative stimulation testing. |
| Guidewire | A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator to pass through more easily. |
| Suture Sleeve Cap | A polyurethane (Pellethane 55D) cap that is placed over the proximal end of the Stimulator. The Sleeve Cap is attached to the Freedom-4 Stimulator and can be sutured to tissue to reduce the possibility of device migration. |

| **Wearable Antenna Assembly (WAA Kit)** | |
|---|---|
| WAA | The WAA device includes the following components sealed within the unit:<br>i. Transmitting (Tx) Antenna – Used to transmit microwave energy to the implanted Stimulator;<br>ii. Microwave Field Stimulator (MFS) – A printed circuit board (PCB) that generates 915 MHz RF power with embedded waveform parameter settings;<br>iii. User Interface (UI) Board – A PCB that contains the circuitry to allow the user to select clinician-programmed parameter combination options or increase or decrease power amplitude;<br>iv. Battery Charger Board and Coil – A PCB and inductive charging coil that receives energy from an external battery-charging unit. The battery charger board communicates with the MFS to transfer charge into the 3.7V battery by facilitating power transfer and warns the system when battery power is low;<br>v. Battery – A lithium ion rechargeable battery. |
| Wireless Battery Charging Pad | A Qi-compliant charging pad that uses inductive charging technology to recharge the encased lithium ion battery of the WAA. |
| Adjustable Strap | An elastic nylon strap that attaches to the two ends of the WAA. This strap can be adjusted to various lengths to accommodate the varying patient population. |

| **Trial Freedom-4 Stimulator (Trial Kit)** |
|---|

| | |
|---|---|
| Trial Freedom-4 Stimulator | A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed percutaneously in the patient's epidural space. The Stimulator has four (4) electrodes. |
| Stylet(s) | A stainless steel wire with a nylon hub that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Four (4) stylets are provided in the Receiver Kit, two straight and two bent with diameters of 0.25 mm or 0.30 mm. |
| Tuohy Needle | A 14-gauge stainless steel needle that is inserted into the epidural space of the patient and acts as a conduit to guide the introducer sheath. |
| Introducer Sheath | A PEBAX sheath that slides over the Tuohy needle before insertion, and acts as a conduit for passage of the stimulator into the epidural space. The introducer sheath is RF transparent, allowing the transmission of wireless power to the Stimulator for intraoperative stimulation. |
| Guidewire | A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator to pass through more easily. |

## 6. Indication for Use Statement

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

## 7. Substantial Equivalence Discussion

The following table compares the Stimwave Freedom SCS System to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence. Stimwave physically measured Medtronic and ANS predicate devices to obtain the values listed in Table 5A.

**Table 5A. Comparison of Characteristics**

| Comparator | Stimwave Freedom SCS System | Medtronic Mattrix 3271/3272 (K934065) | Medtronic Xtrel, Model Number 3425 (K883780) | ANS Renew (K000852) |
|---|---|---|---|---|
| **Product Code** | GZB | GZB and GZF | GZB | GZB |
| **Regulation No.** | 882.5880 | 882.5880 | 882.5880 | 882.5880 |
| **Regulation Name** | Stimulator, Spinal-Cord, Implanted (Pain Relief) | Stimulator, Spinal-Cord, Implanted (Pain Relief) | Stimulator, Spinal-Cord, Implanted (Pain Relief) | Stimulator, Spinal-Cord, Implanted (Pain Relief) |
| **Intended Use** | Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs | Same as Freedom | Same as Freedom | Same as Freedom |

| Comparator | Stimwave Freedom SCS System | Medtronic Mattrix 3271/3272 (K934065) | Medtronic Xtrel, Model Number 3425 (K883780) | ANS Renew (K000852) |
|---|---|---|---|---|
| **Implant Site** | Epidural space, L5 to T5 | Same as Freedom | Same as Freedom | Same as Freedom |
| **Environmental Use** | Hospital, Home | Same as Freedom | Same as Freedom | Same as Freedom |
| **Intended Clinician** | Orthopedic, Neurosurgeon, Anesthesiologist | Same as Freedom | Same as Freedom | Same as Freedom |
| **Intended User** | Layperson | Same as Freedom | Same as Freedom | Same as Freedom |
| **Electrode Material** | Platinum-iridium 90:10 | Same as Freedom | Same as Freedom | Same as Freedom |
| **Stimulator Body Material** | Polyurethane 2363-55D | Same as Freedom | Same as Freedom | Same as Freedom |
| **Cable Features** | Multilumen Tube | Coiled Wires | Coiled Wires | Braided Wire |
| **Stimulator Length** | 45 centimeters | 30 to 110 centimeters | 30 to 110 centimeters | 30 centimeters, and 60 centimeters |
| **Diameter** | 1.35 millimeters | 1.3 millimeters | 1.3 millimeters | 1.37 millimeters |
| **Electrode Array Length** | 24.0 millimeters | Same as Freedom | Same as Freedom | Same as Freedom |
| **No. of Electrodes** | 4 | Same as Freedom | Same as Freedom | 4 or 8 |
| **Electrode Length** | 3.0 millimeters | Same as Freedom | Same as Freedom | Same as Freedom |
| **Electrode Spacing** | 4.0 millimeters | Same as Freedom | Same as Freedom | Same as Freedom |
| **Electrode Surface Area** | 12.72 $mm^2$ | 12.25 $mm^2$ | 12.25 $mm^2$ | "Approximately 13 $mm^2$" |
| **Method of Introduction** | Percutaneous | Same as Freedom | Same as Freedom | Same as Freedom |
| **Tissue Contact** | Yes | Same as Freedom | Same as Freedom | Same as Freedom |
| **Sterilization** | Ethylene Oxide (EO) | Same as Freedom | Same as Freedom | Same as Freedom |
| **Labeling** | Labeled as Sterile, Single Use, Prescription Device | Same as Freedom | Same as Freedom | Same as Freedom |
| **Package** | Blister Tray/Tyvek Lid | Same as Freedom | Same as Freedom | Same as Freedom |
| **Pulse Frequency** | 2 to 1500 Hertz | 5 to 240 Hertz | 5 to 1400 Hertz | 10 to 1500 Hertz |
| **Pulse Width** | 50 to 500 microseconds | 50 to 500 microseconds | 50 to 1000 microseconds | 50 to 500 microseconds |
| **Current/Voltage Regulated** | Current | Voltage | Voltage | Current |
| **Output Voltage (300 Ω)** | 0 to 6.3 V | 0 to 7 V | 0 to 5.4 V | 0 to 5.7 V |
| **Output Voltage (500 Ω)** | 0 to 7.2 V | 0 to 10.8 V | 0 to 7.1 V | 0 to 7.6 V |
| **Output Voltage (800 Ω)** | 0 to 8.0 V | 0 to 11.6 V | 0 to 8.4 V | 0 to 9.6 V |
| **Output Current (300 Ω)** | 0 to 21 mA | 0 to 23.3 mA | 0 to 18.0 mA | 0 to 19.0 mA |
| **Output Current (500 Ω)** | 0 to 15 mA | 0 to 21.6 mA | 0 to 14.2 mA | 0 to 15.2 mA |

| Comparator | Stimwave Freedom SCS System | Medtronic Mattrix 3271/3272 (K934065) | Medtronic Xtrel, Model Number 3425 (K883780) | ANS Renew (K000852) |
|---|---|---|---|---|
| **Output Current (800 Ω)** | 0 to 10 mA | 0 to 14.5 mA | 0 to 10.5 mA | 0 to 12.0 mA |
| **Waveform** | Charge Balanced (delayed) Biphasic asymmetrical | Charge Balanced Biphasic asymmetrical | Charge Balanced Biphasic asymmetrical | Charge Balanced (delayed) Biphasic asymmetrical |
| **Pulse Shape** | Decaying Exponential | Decaying Exponential | Decaying Exponential | Decaying Exponential |
| **Average Current Density (300 Ω)** | 111.6 mA/cm$^2$ | 175.0 mA/cm$^2$ | 125.8 mA/cm$^2$ | 117.7 mA/cm$^2$ |
| **Average Current Density (500 Ω)** | 96.7 mA/cm$^2$ | 151.7 mA/cm$^2$ | 101.7 mA/cm$^2$ | 103.1 mA/cm$^2$ |
| **Average Current Density (800 Ω)** | 77.0 mA/cm$^2$ | 106.7 mA/cm$^2$ | 75.8 mA/cm$^2$ | 86.2 mA/cm$^2$ |
| **Maximum Phase Charge* (300 Ω)** | 10.5 µC/pulse | 11.7 µC/pulse | 18.0 µC/pulse | 9.5 µC/pulse |
| **Maximum Phase Charge* (500 Ω)** | 7.2 µC/pulse | 10.8 µC/pulse | 14.2 µC/pulse | 7.6 µC/pulse |
| **Maximum Phase Charge* (800 Ω)** | 5.0 µC/pulse | 7.3 µC/pulse | 10.5 µC/pulse | 6.0 µC/pulse |
| **Maximum Charge Density* (300 Ω)** | 82.5 µC/cm$^2$ | 97.2 µC/cm$^2$ | 150.0 µC/cm$^2$ | 73.1 µC/cm$^2$ |
| **Maximum Charge Density* (500 Ω)** | 56.6 µC/cm$^2$ | 90.0 µC/cm$^2$ | 118.3 µC/cm$^2$ | 58.5 µC/cm$^2$ |
| **Maximum Charge Density* (800 Ω)** | 39.3 µC/cm$^2$ | 60.4 µC/cm$^2$ | 87.5 µC/cm$^2$ | 46.2 µC/cm$^2$ |
| **Maximum Current Density* (300 Ω)** | 165.1 mA/cm$^2$ | 194.4 mA/cm$^2$ | 150.0 mA/cm$^2$ | 146.2 mA/cm$^2$ |
| **Maximum Current Density* (500 Ω)** | 113.2 mA/cm$^2$ | 180.0 mA/cm$^2$ | 118.3 mA/cm$^2$ | 116.9 mA/cm$^2$ |
| **Maximum Current Density* (800 Ω)** | 78.6 mA/cm$^2$ | 120.8 mA/cm$^2$ | 87.5 mA/cm$^2$ | 92.3 mA/cm$^2$ |
| **Net Charge** | 0 µC | 0 µC | 0 µC | 0 µC |
| **Average Phase Power (300 Ω)** | 0.060 W/phase | 0.132 W/phase | 0.068 W/phase | 0.070 W/phase |
| **Average Phase Power (500 Ω)** | 0.076 W/phase | 0.166 W/phase | 0.074 W/phase | 0.090 W/phase |
| **Average Phase Power (800 Ω)** | 0.060 W/phase | 0.131 W/phase | 0.066 W/phase | 0.100 W/phase |
| **Average Phase Power Density (300 Ω)** | 0.48 W/cm$^2$/phase | 1.10 W/cm$^2$/phase | 0.57 W/cm$^2$/phase | 0.54 W/cm$^2$/phase |
| **Average Phase Power Density (500 Ω)** | 0.59 W/cm$^2$/phase | 1.38 W/cm$^2$/phase | 0.62 W/cm$^2$/phase | 0.69 W/cm$^2$/phase |
| **Average Phase Power Density (800 Ω)** | 0.60 W/cm$^2$/phase | 1.09 W/cm$^2$/phase | 0.55 W/cm$^2$/phase | 0.77 W/cm$^2$/phase |
| **Pulse Delivery Mode** | Continuous | Continuous | Continuous | Continuous |

| Comparator | Stimwave Freedom SCS System | Medtronic Mattrix 3271/3272 (K934065) | Medtronic Xtrel, Model Number 3425 (K883780) | ANS Renew (K000852) |
|---|---|---|---|---|
| **ON/OFF Times** | No Cycling | ON/OFF Cycling Option | ON/OFF Cycling Option | No Cycling |
| **Current Path Options** | Bipolar | Bipolar | Bipolar | Bipolar |
| **Power Delivery** | Coupled receiver, built into Stimulator body | Coupled receiver, Radio Frequency transmission | Coupling receiver, Radio Frequency transmission | Coupled receiver, hardwired with connector |
| **Transmit Frequency** | 915 MHz | 2 MHz | 1.60 MHz | 2 MHz |
| **Material** | Platinum-iridium 90:10, Polyurethane 2363-55D | Same as Freedom | Same as Freedom | Same as Freedom |
| **Sterile** | Yes - ethylene oxide | Same as Freedom | Same as Freedom | Same as Freedom |
| **Single-Use** | Yes | Yes | Yes | Yes |
| **Shelf Life** | 1 year | 1 year | 1 year | 2 years |
| **Complies with ISO 10993-1** | Yes | Yes | Yes | Yes |
| **Safety Testing Passed** | Yes | Yes | Yes | Yes |

**(*) asterisk denotes that formulas were used for the calculations.**

## 8. Biocompatibility Data

The Freedom SCS System biocompatibility tests were conducted on representative subassemblies of the product. The materials, construction and intended use of the Freedom SCS System is comparable to the predicate device, and have a long history of safety with respect to biocompatibility. The biological safety of the Freedom-4 Stimulator was evaluated in accordance to ISO 10993-1:2009 and guidance document Blue Book Memorandum G95-1 *Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, the device was classified as a (C), implant device in contact with tissue/bone. The results for the biocompatible testing for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation (4, 8, and 13 weeks), and subchronic toxicity demonstrated no negative impacts from the materials that are used in the Freedom SCS System. The Freedom-4 Stimulator materials in direct tissue contact include Pellethane 55D and Pt-Ir (90:10), both having an extensive record (previously cleared and approved) of subchronic toxicity, chronic, and carcinogenetic safety. The WAA is intended to be on top of a thin shirt or article of clothing around the midsection of the patient. The User Manual provided to the patient describes that the WAA should always be worn on top of a layer of clothing. The WAA does not come into contact with the patient's skin. The categorization by nature of body contact of the WAA is thus "non-contacting device", and not included in the scope of ISO 10993-1:2009. The Freedom SCS System meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

## 9. Non-Clinical Performance Data

The Freedom SCS System was tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The Freedom SCS System complies with all design requirements and applicable voluntary standards.

**AAMI ANSI ISO 14708-3:2008** - For protection from temperature change including shipping and storage temperature ranges, the Freedom-4 Stimulator was functional, receiving a safe rating following post visual inspection and passed the change of temperature testing performed as specified by AAMI ANSI ISO 14708-3:2008.

For atmospheric pressure change, the Freedom-4 Stimulator was functional following post testing functionality inspection and passed atmospheric pressure change testing as specified by AAMI ANSI ISO 14708-3:2008.

For magnetic resonance imaging (MRI) radio frequency (RF) induced heating as related to specific absorbance rate (SAR), the Freedom-4 Stimulator produced a maximum temperature increase lower than the allowable limit for the 1.5T and 3T MRI procedure and thus passed the 1.5T and 3T testing.

**ASTM F2182-11a** - In accordance with F2182-11a – American Society for Testing and Materials (ASTM) International Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, the Freedom-4 Stimulator showed that its presence would not cause injury to the patient with the implant during an MRI procedure. The Freedom-4 Stimulator is a passive implant that is not powered while the external unit is not transmitting to it. For MRI exposure, RF image artifact testing, the Freedom-4 Stimulator produced a maximum measured artifact size lower than the allowable limit for the 3T MRI procedure and thus passed the testing.

**ASTM F2119-07** - In accordance with F2119-07 – American Society for Testing and Materials (ASTM) International Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, the Freedom-4 Stimulator showed that it does not produce image artifacts in 3T MRI procedures that are detrimental to the outcome of the procedure. For MRI exposure, induced displacement, the Freedom-4 Stimulator produced a significantly lower deflection value than the allowable test limit.

**ASTM F2052-06** - In accordance with F2052-06 – The American Society for Testing and Materials (ASTM) International Designation Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, the Freedom-4 Stimulator showed that it does not harm the patient due to its displacement by forces induced by MRI exposure. The Freedom-4 Stimulator passes the ASTM acceptance criteria for deflection angle in a 3T MRI system and will not present an additional risk or hazard to a patient in the 3T or less MRI environment. For MRI exposure, induced torque, the Freedom-4 Stimulator produced the lowest score, no torque, according to the qualitative scale outlined by the applicable

ASTM standard.

**ASTM F2213-06** - In accordance with F2213-06 – American Society for Testing and Materials (ASTM) International Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment, the Freedom-4 Stimulator must show that it does not harm the patient due to its torque by forces induced by MRI exposure. The Freedom-4 Stimulator will not present an additional risk or hazard to a patient in the 3T MRI environment or less with regard to torque. The stimulation waveforms following post-exposure showed no component damage had occurred in any stimulator. During testing, no component damage was observed in any waveform. Based on these test results, the Freedom-4 Stimulator will be fully functional following standard 1.5T and 3T MR procedures and its performance or functionality is not affected by such exposures. Following the thermal shock testing, the Freedom-4 Stimulator was found to have "no irreversible damage" and fully functional as specified by the manufacturer, and to have no physical anomalies present at the time of inspection. Thus, the Freedom-4 Stimulator complies with the thermal shock design requirements and the applicable standard. For leakage current testing, the Freedom-4 Stimulator produced zero leakage current on all tested paths for all tested samples. Thus, the Freedom-4 Stimulator complies with the leakage design requirements and the applicable standard. For testing the insertion and withdrawal of the stimulator within the stylet, the Freedom-4 Stimulator was found to require less than 2.5N of insertion or withdrawal force for all tested stylets in all tested stimulator samples. Visual inspection confirmed no damage was present in any stimulator samples.

Thus, the Freedom-4 Stimulator complies with all design. For stimulator body flex testing, the Freedom-4 Stimulator passed all criteria of the test, showing no visible damage to the stimulator body or the components. Thus, the Freedom-4 Stimulator complies with all stimulator body flex test design requirements. For transition stimulator body to the flex board, the Freedom-4 Stimulator passed all criteria of the test with no visible damage to the segment. For the destructive pull test, the Freedom-4 Stimulator was verified to function as outlined by the criteria of the test and the maximum elongation found in all samples was 0.5%, well below the test limit of 5%. For testing external defibrillation exposure, the Freedom-4 Stimulator was verified to function as outlined by the criteria of the testing protocol.

**IEC 60601-1** - For testing the external unit for protection from temperature change, including shipping and storage temperature ranges, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the external unit of the Freedom SCS System satisfies the outlined protection from temperature change design requirements and the applicable standard, IEC 60601-1. For atmospheric pressure change testing, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the external unit of the Freedom SCS System satisfies the outlined atmospheric pressure change design requirements and the applicable standard, IEC

60601-1. For the push, drop, impact and mold stress relief testing of the external unit, it was determined through testing that the external unit is robust to withstand expected damage in accordance with general safety standards. The external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom SCS System satisfies the outlined push, drop, impact, and mold stress relief design requirements and the applicable standard, IEC 60601-1. For the identification, marking and documents of the external unit it was determined through an analysis of the labeling that the external unit complies with the requirements of the standard. All requirements and markings are clearly identified and viewable either from the external case of the product or from within the accompanying documents. For the means of protection, creepage distances, and air clearances of the external unit it was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1.

**IEC 60601-1-2** – For testing the external unit for electromagnetic compatibility, the unit met all acceptance criteria for emissions, low-frequency magnetic fields, immunity, electrostatic discharge, radiated RF electromagnetic fields, electrical fast transients and bursts, and magnetic fields. The external unit operated within all test limits and showed no physical damage and was fully operational. Thus, the external unit for the Freedom SCS System satisfies the IEC 60601-1-2 standard.

**IEC 60529** - For testing the ingress of water, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom SCS System satisfies the outlined Ingress of Water design requirements and the applicable standard IEC 60529. For particulate matter testing, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom SCS System satisfies the outlined Particulate Matter design requirements and the applicable standard, IEC 60529. The software of the Freedom SCS System passed all verification tests outlined and the design requirements for Software Verification have been met.

The Freedom SCS System complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

Following performance testing, it has been determined that the Freedom SCS System is substantially equivalent to legally marketed predicate devices for the therapy for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

Stimwave Technologies Incorporated completed a number of tests for the Freedom SCS System that demonstrates substantial equivalence to the legally marketed predicate devices. The Freedom SCS System meets all the requirements for overall design,

sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The Freedom SCS System passed all testing stated above as shown by the acceptable results obtained.

**10. Clinical Performance Data**

There was no clinical testing required to support the medical device as the indications for use is equivalent to the legally marketed predicate device. These types of devices, including the legally marketed predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

**11. Statement of Substantial Equivalence**

By definition, a device is substantially equivalent to legally marketed predicate devices when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The Freedom SCS System has the same intended use as the legally marketed predicates devices and is implanted percutaneous into the epidural space ranging from T5 to L5. Performance tested verified that the Freedom SCS System complies with all applicable voluntary standards such as IEC 60601-1, AAMI ANSI ISO 14708-3, IEC 60529 and MRI safety tests. The Freedom SCS System also meets the design requirements where no applicable standard could be used. This included stimulator body durability testing, programmable parameters, as well as power and performance of the external unit. There were no recognized performance standards for this device. There was no clinical testing performed on this device since performance testing demonstrated similar performance as the legally marketed predicate devices, and materials for the implanted stimulator are the same as the legally marketed predicate devices.

It has been shown in this 510(k) submission that the difference between the Freedom SCS System and the legally marketed predicate devices do not raise any questions regarding its safety and effectiveness as compared to legally marketed predicate devices. Freedom SCS System, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate devices.